Nov. 5, 2021: National Advocacy Update

New national opioid treatment program resource to support evidence-based care

The American Association for the Treatment of Opioid Dependence (AATOD) recently issued a new resource that begins with a helpful perspective on the formation, growth and regulatory history of the 1,200 opioid treatment programs (OTP) in the United States and provides policy recommendations to increase access to OTPs.

In addition to making recommendations to further support evidence-based patient care, the AATOD resource provides analysis of OTP and patient experience during COVID-19. This includes highlighting the importance of continuing increased flexibilities for take-home medication, dispensing requirements, insurance coverage and reimbursement policies and how certain state-based restrictions (e.g., zoning and siting requirements) continue to be barriers to further OTP development.

Among the paper’s 13 recommendations is the need to increase the use of mobile vans to provide medications to treat opioid use disorder (MOUD) for rural and underserved areas, in jails and prisons, and to support residential recovery and treatment facilities. The AMA recently lauded the DEA’s new flexibilities for states to use mobile vans.

The new AATOD resource also discusses the need for changes to better support satellite treatment facilities, telehealth services and communications efforts with state and federal authorities to help destigmatize evidence-based treatment options with MOUD.

Alternative payment model (APM) update

The founder of SonarMD, Inc., Larry Kosinski, MD, an Illinois gastroenterologist and AMA member, has been appointed to the federal advisory committee on physician-designed APMs, known as the PTAC, for a three-year term. Dr. Kosinski’s proposal to the PTAC for Project Sonar, a value-based care coordination solution for patients with complex chronic conditions, was the first APM proposal that the committee recommended to the Secretary of Health and Human Services (HHS). It was also announced that Jennifer Wiler, MD, professor of emergency medicine at the University of Colorado School of Medicine, who has served on PTAC since 2018, has been reappointed for another three-
year term.

The PTAC appointments come at the same time that the Center for Medicare and Medicaid Innovation (CMMI) has published its "strategy refresh," describing new objectives for CMMI based on its experience with APMs during its first ten years. A number of the policies outlined in the new CMMI strategy are very encouraging as they would implement recommendations made to CMMI leadership last spring in a letter (PDF) from the AMA and many national specialty societies as well as several meetings. These include CMMI plans to:

- Make APM parameters, requirements and other critical details as transparent and easily understandable as possible for participants.
- Reduce administrative burdens from APM participation requirements.
- Make available and increase uptake of actionable data, learning collaboratives and payment and regulatory flexibilities to participants, especially those treating the underserved.
- Improve testing and analysis of benchmarks and risk adjustment methods.
- Deepen and sustain outreach and solicitation of input from patient and physician groups.
- Explore model tests for specialty care payment models.
- Identify ways to align or integrate episode payment models with accountable care models.

AMA asks OCR for telemedicine HIPAA compliance glidepath

The AMA recently wrote (PDF) to the HHS Office for Civil Rights (OCR) regarding enforcement of the Health Insurance Portability and Accountability Act (HIPAA) regulations in the context of telemedicine during the COVID-19 public health emergency (PHE). Early in the PHE, OCR recognized that physician practices would need to quickly adopt telemedicine technologies to help provide safe and accessible care to their patients. To help support such adoption, OCR announced its policy of using discretion in enforcing HIPAA violations for physicians and hospitals who, in good faith, utilized telemedicine platforms and applications to connect with their patients.

The AMA supported this policy as it helped clinicians quickly adopt telemedicine without needing to first implement contracts and security reviews that are often complicated and time-consuming. Of course, while HIPAA compliance may seem onerous and burdensome, it is a necessary ingredient to the long-term continued use and success of telemedicine technology. HIPAA’s requirements are intended to ensure that both clinicians and their business associates are accountable for the privacy and security of patient information, thereby fortifying the trust that is central to the physician-patient relationship.

Simultaneously, physicians have had to adapt to new technologies to deliver virtual care while also managing multiple stressors on their practices, in-person patients and staff during an incredibly
demanding and difficult pandemic. They will need time once the PHE ends to ensure that their policies, procedures, risk analyses and business associate agreements are in order. Accordingly, when the PHE declaration ends, the AMA is urging OCR to establish a one-year glidepath to compliance, during which physicians and other affected parties shall not be subject to HIPAA audits and other HIPAA enforcement activity related to telemedicine.

**AMA asks OCR and CDC to protect patient vaccination data**

The AMA recently wrote to OCR and Centers for Disease Control and Prevention (CDC), urging the agencies to prevent inappropriate use of patient information collected for COVID-19 vaccination scheduling or administration. The AMA firmly opposes the sale or transfer of medical history data and contact information accumulated through the scheduling or provision of government-funded vaccinations to third parties for use in marketing or advertising. Unfortunately, reports have surfaced that some large retail pharmacies are collecting a significant amount of medical history and contact information from patients seeking to schedule COVID-19 vaccinations, sometimes even for those merely seeking to see if an appointment is available. Unchecked data collection, sharing and processing amplifies discrimination (PDF) based on race, gender, sexual orientation, ability, age, financial status and other group membership. It can lead to the development of risk scores by a wide range of companies, including health insurers, yet most people are not even aware these scores exist. Failing to address such misuse of data will contribute to declining levels of trust (PDF) in our nation’s public health agencies and infrastructure.

The AMA is also concerned that some larger retail pharmacy chains may see this as an opportunity to recruit patients to utilize their retail health clinics for routine visits in competition with a patient’s medical home. The CDC has issued guidance to providers titled, Use of Vaccine Recipient Data for Commercial Marketing Purposes Prohibited, stating that "providers are prohibited from using or disclosing data collected from vaccine recipients for and through the CDC COVID-19 Vaccination Program for commercial marketing purposes or for any other purpose not allowed under this updated provision of the COVID-19 Vaccination Provider Agreement." The AMA has urged the federal government to act swiftly in reiterating and clarifying necessary protections to ensure retail pharmacies do not, whether intentionally or inadvertently, misuse patient data they collect during the COVID-19 vaccination scheduling and/or the vaccine administration process.

**AMA encourages CMS to improve prior authorization practices in Medicare Advantage plans**

On June 28, Senators Brown (D-OH) and Thune (R-SD) sent a bipartisan letter (PDF) with 27
bipartisan cosigners to CMS Administrator Chiquita Brooks-LaSure urging CMS to adopt a bipartisan plan to improve prior authorization (PA) practices in Medicare Advantage (MA) Plans. The letter encourages CMS to use their bipartisan legislation, S. 3018, the Improving Seniors Access to Timely Care Act, as the framework to require private insurance companies that operate MA plans to adopt electronic PA programs and approve medical services in a more timely manner.

In an AMA survey conducted in Dec. 2020 of 1,000 practicing physicians on their experience with PA during COVID-19, 94% of physicians saw care delays (PDF) with patients waiting for needed care and 79% of physicians saw patients stop treatment due to prior authorization practices. The bill would help streamline PA processes and promote safe, timely and affordable access to care for MA enrollees and the providers and suppliers who treat them. The bill has been referred to the Senate Finance Committee.

The AMA is also a supporter of the companion bill, H.R. 3173, introduced by Rep. DelBene (D-WA-1) which has 239 bipartisan cosponsors and has been referred to the House Ways and Means Committee and the House Energy and Commerce Subcommittee on Health. The AMA will continue its advocacy on this important legislation to see this barrier to patient care addressed for MA enrollees.

**AMA urges FDA to re-evaluate human tissue donation policy for men who have had sex with men**

The AMA sent a letter to the FDA (PDF) urging them to re-evaluate a policy requiring a five-year deferral period for men who have had sex with men (MSM) with regards to donating human cells, tissues and cellular and tissue-based products (HCT/P), including corneas. AMA policy supports the use of "rational, scientifically-based blood and tissue donation deferral periods that are fairly and consistently applied to donors according to their individual risk." The AMA strongly encourages HCT/Ps deferral policy to be in alignment with the current science as well as consistent with the ethical treatment of donors.

The AMA applauds the FDA’s funding of research into individual risk assessments for blood donation, such as through the Assessing Donor Viability And New Concepts in Eligibility (ADVANCE) study, and encourages the FDA to expand this work to include HCT/Ps donation deferrals as well. Current guidelines require MSM to defer HCT/Ps donation for five years since their last sexual contact with a man. These guidelines arose out of the HIV epidemic of the 1980s and 1990s in which MSM were at higher risk of HIV transmission and HIV tests were lacking in accuracy and precision. This deferral period is not consistent with the guidelines for other groups of comparable or higher risk.

The AMA encourages the FDA to expeditiously revise its HCT/Ps donor deferral policy to be in alignment with blood donation policy and to use the ADVANCE study or other similar research.
programs, as an opportunity to adopt individual risk assessment for HCT/Ps donors.

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